

<b>Title:</b> Review of Section 24 of the Animals (Scientific Procedures) Act 1986. <b>IA No:</b> HO-0104 <b>Lead department or agency:</b> Home Office <b>Other departments or agencies:</b> Department of Business, Innovation and Skills, Ministry of Justice, Information Commissioner's Office.	<b>Impact Assessment (IA)</b>		
	<b>Date:</b> 07/02/2014		
	<b>Stage:</b> Consultation		
	<b>Source of intervention:</b> Domestic		
	<b>Type of measure:</b> Primary legislation		
<b>Contact for enquiries:</b> Will Reynolds, Animals in Science Regulation Unit, 02070350454.			
<b>Summary: Intervention and Options</b>		<b>RPC Opinion:</b> Not Applicable	

Cost of Preferred (or more likely) Option			
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Two-Out? Measure qualifies as
NA	NA	NA	No NA

**What is the problem under consideration? Why is government intervention necessary?**  
Section 24 of the Animals (Scientific Procedures) Act 1986 (ASPA) is a statutory prohibition on disclosure that provides for the protection of information received in confidence that is provided in connection with our regulatory activities under the 1986 Act. A breach of section 24 can result in criminal sanctions. The Government is reviewing Section 24 since its inflexible confidentiality requirements are now out of step with government policy on openness and transparency and with the approach taken in other legislation, such as the Freedom of Information Act 2000. In addition, there is a lack of understanding as to the application of Section 24 and therefore the information that can be released.

**What are the policy objectives and the intended effects?**  
There is a lack of clarity as to the extent to which the current legislation can be applied and the information covered by it released. There is a requirement for a more flexible framework that will protect personal safety, proprietary rights and intellectual property, while providing greater transparency to assist public understanding about the use of animals in scientific procedures. It is imperative that the amended legislation does not harm the competitiveness of the UK in the life sciences and retains the confidence and trust of the UK life sciences sector (and the public) in our duties as a regulator. Any changes must not fetter the intent of ASPA. It is not our objective to provide information so the public or other external bodies can conduct their own harm / benefit analysis as to whether a particular project should be initiated.

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**  
Policy options under consideration, in advance of a public consultation, are:  
Option 1 - Retain Section 24 of the Act (do nothing). This currently provides a statutory prohibition on disclosure of information provided in confidence, and creates a criminal offence.  
Option 2.a - Repeal Section 24 and amend ASPA, creating a criminal offence of malicious disclosure of information about the use of animals in scientific research.  
Option 2.b - As option 2.a. The legislative framework would additionally include a statutory prohibition on disclosure of information relating only to people and place details and intellectual property.  
Option 3 - Repeal Section 24.  
The preferred option is 2.b, for the reasons outlined in the evidence base.

<b>Will the policy be reviewed?</b> It will be reviewed. <b>If applicable, set review date:</b> 01/2017					
Does implementation go beyond minimum EU requirements?				Yes	
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.		<b>Micro</b> Yes	<b>&lt; 20</b> Yes	<b>Small</b> Yes	<b>Medium</b> Yes
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)				<b>Traded:</b>	
				<b>Non-traded:</b>	

*I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.*

Signed by the responsible SELECT SIGNATORY: \_\_\_\_\_ Date: \_\_\_\_\_

# Summary: Analysis & Evidence

# Policy Option 2.a

**Description:** Repeal Section 24 and amend ASPA, creating a criminal offence of malicious disclosure of information about the use of animals in scientific research.

## FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	NA	NA	NA

### Description and scale of key monetised costs by 'main affected groups'

It has not been possible to quantify any costs.

### Other key non-monetised costs by 'main affected groups'

UK bioscience sector (UKBS) and Government - There is an increased amount of information that would need to be either proactively or reactively made publicly available. There could be an increase in FOI requests which would most likely have an impact in the short term following a reduction in the extent to which ASPA precludes disclosure under FOIA. Legislative changes to greater transparency may have some resource implications for the greater provision of publicly accessible information

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	NA	NA	NA

### Description and scale of key monetised benefits by 'main affected groups'

It has not been possible to quantify any benefits.

### Other key non-monetised benefits by 'main affected groups'

Public – Greater ease to obtain information in a transparent way. Enhanced understanding of work conducted under ASPA. Potential to highlight threats to animal welfare without fear of criminal sanction. UKBS and Government - Assurance that information provided in confidence to the Government retains appropriate (clarified) protection, and alternative protection to that provided by FOIA. Reduced risk of challenge of not providing information due to increased clarity of the legislation, possibly leading to a less bureaucratic system.

Key assumptions/sensitivities/risks	Discount rate (%)	NA
<p>UKBS - An increase in the amount of publicly available information may lead to an increased risk of identification of key confidential information. This may endanger public health and safety or the commercial competitiveness of the UKBS.</p> <p>Government - The creation of a criminal offence may have a downstream impact on the criminal justice system.</p>		

## BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:	In scope of OITO?	Measure qualifies as
Costs: NA      Benefits: NA      Net: NA	No	NA

# Summary: Analysis & Evidence

# Policy Option 2.b

**Description:** As option 2.a. The legislative framework would additionally include a statutory prohibition on disclosure of information relating only to people and place details and intellectual property.

## FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	NA	NA	NA

### Description and scale of key monetised costs by 'main affected groups'

It has not been possible to quantify any costs.

### Other key non-monetised costs by 'main affected groups'

UKBS and Government - There is an increased amount of information that would need to be either proactively or reactively made publicly available. There could be an increase in FOI requests which would most likely have an impact in the short term following a reduction in the extent to which ASPA precludes disclosure under FOIA. Legislative changes to greater transparency may have some resource implications for the greater provision of publicly accessible information.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	NA	NA	NA

### Description and scale of key monetised benefits by 'main affected groups'

It has not been possible to quantify any benefits.

### Other key non-monetised benefits by 'main affected groups'

Similar to those in option 2.a, however there would be greater assurance (for UKBS and Government) that information provided in confidence by duty holders to the Government retains appropriate (clarified) protection, and alternative protection to that provided by FOIA, due to the addition of a statutory prohibition on disclosure of information that relates only to people and place details and intellectual property. This may mitigate concerns of insufficient protection of confidential information and a threat to investment in UKBS.

Key assumptions/sensitivities/risks	Discount rate (%)	NA
The risks would be similar to those for option 2.a. However, the addition of a statutory prohibition on disclosure for information relating only to people and place details and intellectual property may mitigate some of the risks detailed in option 2.a regarding insufficient protection for confidential information.		

## BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:	In scope of OITO?	Measure qualifies as
Costs: NA	No	NA
Benefits: NA		
Net: NA		

# Summary: Analysis & Evidence

# Policy Option 3

**Description:** Repeal Section 24 of the Animals (Scientific Procedures) Act 1986.

## FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	NA	NA	NA

### Description and scale of key monetised costs by 'main affected groups'

It has not been possible to quantify any costs.

### Other key non-monetised costs by 'main affected groups'

UKBS and Government - There is an increased amount of information that would need to be either proactively or reactively made publicly available. There could be an increase in FOI requests which would most likely have an impact in the short term following a reduction in the extent to which ASPA precludes disclosure under FOIA. Legislative changes to greater transparency may have some resource implications for the greater provision of publicly accessible information.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	NA	NA	NA

### Description and scale of key monetised benefits by 'main affected groups'

It has not been possible to quantify any benefits.

### Other key non-monetised benefits by 'main affected groups'

UKBS and Government – There is a reduced risk of challenge, and successful challenge, of not providing information as the present provisions under Section 24 lack clarity. Dependent on the delivery mechanism of information, this could be a less bureaucratic system.  
Public – Greater ease to obtain information in a transparent way. Enhanced understanding of work conducted under ASPA.

Key assumptions/sensitivities/risks	Discount rate (%)	NA
UKBS and Government - Increased vulnerability to loss of key confidential information. Assumption that the risk of malicious disclosure is minimal and that the inappropriate release of confidential information is either unlikely or does not require a criminal sanction. Significant risk of the UK appearing to provide insufficient protection to confidential information. This may lead to an increased loss of investment in the UKBS, with a resultant negative impact on UK economic growth.		

## BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: NA	Benefits: NA	Net: NA	No	NA

# Evidence Base (for summary sheets)

## A. Strategic Overview

### A.1 Background

#### Review of Section 24 - Animals (Scientific Procedures) Act 1986.

#### Issue and purpose

The Animals (Scientific Procedures) Act 1986 (ASPA) provides for the protection of animals used for experimental or other scientific purposes. Section 24 (S24) of the Act prohibits the disclosure of information given in confidence that relates to the use of animals in scientific procedures, other than in the discharge of a person's functions under ASPA. It creates a criminal offence and provides a maximum punishment of two years imprisonment and a fine for unauthorised disclosure of information.

S24 was included in ASPA to provide assurance to individuals and establishments applying for authorisations, and subsequently carrying out projects, that confidential information and intellectual property provided to the competent authority would be protected. Primarily, the intent was to prevent the disclosure of information, held under ASPA, by the regulatory authority.

S24 was reviewed in 2004 as part of a Government-wide exercise to review statutory bars in the run up to the introduction of public access rights under the Freedom of Information Act 2000 (FOIA). The review<sup>1</sup> concluded that it should be retained until the effect of the public access rights was known.

In a 2008 judgment, the Court of Appeal concluded that S24 raises a simple question of fact: does the official or other person receiving information know or have reasonable grounds for believing that the relevant information was given in confidence?

In the light of this ruling, determining whether S24 applies in a particular case (in terms of believing the relevant information was given in confidence) is relatively straightforward. However, a lack of clarity arises over who can apply it and how (e.g. the Home Office can, but higher education establishments largely cannot). S24 allows no flexibility, so that, technically, Government officials should not disclose information covered by S24 even if the provider of the information has no objection to its disclosure. Officials might also be in breach of S24 if they disclose information which has already entered the public domain.

Evidence submitted to the House of Commons Justice Select Committee during post-legislative scrutiny of the FOIA raised Section 24 as a concern, in particular regarding the lack of clarity it provides and how some institutions may be vulnerable to prosecution if they release information under FOIA. In response, the Committee stated that "*As section 24 of the Animal (Scientific Procedures) Act 1986 remains under review by the Home Office following changes in European law we make no recommendation as to how the Government should act but will consider the outcome of the review when it is received. It should not be necessary to amend the Freedom of Information Act to meet the concerns of universities in this area.*" The Government agreed with the Committee's approach, commenting that in any event it would be inappropriate to amend ASPA through a review of FOIA, especially given the Home Office's separate review of S24.

The inflexibility of S24 is clearly out of step with the government's attitude to promoting a climate of openness and transparency. Stakeholder engagement has demonstrated a lack of understanding over the application of the current legislation and the overlap with the protection provided for sensitive information by FOIA. There is a requirement for a more flexible framework that will protect proprietary rights, intellectual property and personal safety, while providing greater transparency to assist public understanding. It is imperative that the amended legislation does not harm the competitiveness of the UK in the life sciences and retains the confidence and trust of the UK life

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<sup>1</sup> Review of Statutory Provisions on Disclosure: Department for Constitutional Affairs

sciences sector (and the public) in our duties as a regulator. It should be noted that ASPA, under which the Animals in Science Regulation Unit operates, is unique in that it requires by law applicants to disclose details of high value assets – such as intellectual property or commercially valuable research ideas – in order to gain authorisation to perform the scientific research in question. Consequently, balancing a commitment to openness with the provision of the requisite protection for sensitive information is of paramount importance.

We took this review forward over 2013 through interactive stakeholder workshops (with attendees from across the diversity of opinion) and the key issues from these were taken to further (separate) stakeholder engagements in order to develop a range of policy options. These engagements were held with the UK bioscience sector (UKBS), research funding bodies, animal welfare groups, animal protection groups, practitioners and others with an interest in the use of animals in scientific research. Expert advice has also been sought from partner departments Ministry of Justice, Home Office Legal Adviser's Branch and the Department for Business, Innovation and Skills; and also the Information Commissioner's Office, responsible for regulating the use of S24 to prevent disclosure under FOIA.

## **Current Legislation**

Section 24 of Animals (Scientific Procedures) Act 1986 (ASPA)

*Protection of confidential information.*

- 1) *A person is guilty of an offence if otherwise than for the purpose of discharging his functions under this Act he discloses any information which has been obtained by him in the exercise of those functions and which he knows or has reasonable grounds for believing to have been given in confidence.*
- 2) *A person guilty of an offence under this section shall be liable—*
  - a) *on conviction on indictment, to imprisonment for a term not exceeding two years or to a fine or to both;*
  - b) *on summary conviction, to imprisonment for a term not exceeding six months or to a fine not exceeding the statutory maximum or to both.*

## **Scope of information held under Section 24**

Section 24 of the Act relates to information which has been obtained in the exercise of functions under the ASPA (1986) and which there are reasonable grounds for believing to have been given in confidence.

The lists below (licensing and Inspections) itemise some of the information which might be covered by Section 24 where it contains material provided in confidence by licence applicants. However, they are not exhaustive (not all of the types of information listed below are equally covered). For instance, Section 24 may only cover some parts of a licence assessment – information within Home Office-generated documentation is only covered to the extent that it repeats information provided in confidence. Furthermore, Section 24 may apply to parts of other information sources which indirectly reference information provided in confidence through the function of ASPA, such as policy advice to Ministers and legal advice.

### **a) Licensing**

- Licence applications (personal, project and establishment), supplementary information and associated correspondence
- Assessments of licence applications by inspectors
- Animals in Science Committee (ASC) and external assessor advice on project applications
- Infringement correspondence
- Section 12 (ASPA) review papers/proceedings (including legal advice and final report)

### **b) Inspections**

- Inspection visit reports
- Risk assessments of establishments
- Infringement reports

- Other information provided by licensees and establishments
- Information provided by (and about) overseas suppliers and our assessment

**c) Other**

- ASC records
- Ministerial and policy advice

### **Outline of the review of Section 24**

The review of Section 24 is part of the Government drive for greater transparency. The new framework must provide confidence about that information which is protected by Section 24 (or the chosen framework following the review) and that which is not, alongside clarification of who may rely on it. A new framework must not fetter the primary intent of the Act which is to protect the welfare of animals that are used under procedure.

Through stakeholder engagement we have developed a clearer picture of the outcomes of the new framework in terms of information that *must* be protected whilst retaining openness on information that could be disclosed. However, information will not necessarily remain sensitive forever e.g. researchers publish their work after their studies are completed and they provide their location in such publication etc.

Information that *must* be protected so long as it remains sensitive, and therefore not in the public interest to be released, includes that about:

- **Individuals or precise locations** – this includes information that could directly or indirectly lead to the identification of such details, so as to protect the health and wellbeing of all those involved in the research, in particular against unlawful activity.
- **Commercially sensitive information and intellectual property (IP)** – these are the ideas of research scientists which, if subsequently proven, may be publishable in academic journals, patentable or become subject to copyright. This includes information describing novel ideas, protocols, procedures, experiments, inventions or other IP (including but not limited to information intended for future publication or commercialisation).

The new framework, following completion of the review of Section 24, should also:

- Not negatively impact on the competitiveness of UK life sciences, either through insufficient levels of protection provided to confidential information or a disproportionate regulatory burden placed on private or public research bodies. The proposed amendments to the legislation go beyond minimum EU requirements in terms of the amount of information that is potentially publicly accessible (subject to the exemptions within FOIA).
- Aim for flexibility and consistency in the release of information, e.g. if research has been published identifying an institution or organisation, the legislation would also provide for release of the same information when held by the Home Office / Government. There should also be flexibility to permit disclosure of some information in controlled circumstances e.g. to protect health and well being of individuals.
- Provide clarity about who the legislation applies to and the scope of its coverage. This includes clarity for licensees / establishments as to what information may or may not be released and when, in order to maintain confidence and trust in the regulatory process. Within this, it will be necessary to ensure that any sanctions against inappropriate disclosure are sufficient / proportionate.

## **A.2 Groups Affected**

The main affected groups (consistent for all policy options) will be those with key interests in the animals in science agenda. Greater transparency will result in an increase in the amount of information that could potentially be released into the public domain. The extent of the affect this increased openness will have on each group is dependent on the chosen option. The main affected groups include:

- **Government - Officials**

This group will likely be subject to further scrutiny due to the release of further information, and consists of:

- a) **Home Office:** The Home Office is the main government department affected by any possible changes to the legislation, should they be implemented. The assessment of the individual, project and establishment licences necessary to operate under ASPA is performed by the ASRU inspectorate who may encounter an additional regulatory burden (e.g. the establishment of new systems and processes).
- b) **Business, Innovation and Skills:** This Department may also be affected in terms of their interest in maintaining and developing a strong UK life sciences sector. There is a possible strain on workload and stifling of innovation, which in turn may negatively impact on the economic growth of the UK.
- c) **Ministry of Justice,** given its policy responsibility for FOIA and funding of the ICO in relation to FOI matters. Additionally, the creation of a new criminal offence may have an impact on the criminal justice system, with potential impacts on the Crown Prosecution Service, HM Courts and Tribunal service, legal aid, prisons and probation services. (Note: The Ministry of Justice Court Proceedings Database holds information on defendants proceeded against, found guilty and sentenced for criminal offences in England and Wales. This database holds information on offences provided by the statutes under which proceedings are brought but not all the specific circumstances of each case. It is not possible for us to identify from centrally held information how many defendants were proceeded against for offences under the current Section 24 of ASPA, as triable-either-way offences under ASPA are recorded on the Court Proceedings Database as part of a miscellaneous group, which cannot be separately analysed).

- **Information Commissioner, Courts and Tribunals**

- d) **Information Commissioner's Office,** given its respective responsibilities for the enforcement of FOIA, including in relation to any changes to the effect of Section 24 and changes in the numbers of requests and appeals received.
- e) **Tribunals and Courts.** The First Tier Tribunal (Information Rights), Upper Tribunal, and higher courts would have to consider any appeals against relevant ICO decision notices taking account of any changes to Section 24. Further to that mentioned in point (c), the criminal justice system would need to take account of any changes to Section 24 in the context of prosecutions brought for any unlawful disclosures made outside FOIA context.

- **The UKBS that conducts work under ASPA.**

This can be broken down into industry (contract research, medical etc.) and academia. As of January 2014, there were 15,968 individuals holding ASPA personal licences, 2,667 project licences in force and 174 licensed establishments. These establishments can be broken down as follows:

<b>Type of establishment</b>	<b>Number</b>
Public health	3
Higher education	74
Quango	19
NHS hospital	3
Government department	8
Non-profit making organisation	14
Commercial	53

- a) **Public and private sector - contribution to UK economy:** Nearly 30% of all money spent on research and development in the UK is on pharmaceutical research, accounting for £4.6 billion, and life sciences accounts for 8% of the UK manufacturing sector (by gross value added). The sectors dependent on the use of animals for experimental and other scientific purposes have an estimated 100,000 employees, many in highly-skilled and highly-paid jobs. These sectors make a significant contribution to the UK economy. This contribution to the UK economy may be at risk if the UK is perceived as too high-risk an environment to operate in, both in terms of a perception of insufficient protection of sensitive information and / or being placed under a disproportionate regulatory burden.
- b) **Public and private sector – release of information:** There is a potential release of more information than at present. There may be a cost incurred relating to establishing new systems and processes to provide for the consistent dissemination of information, including (but not limited to) responding to FOI requests. FOIA does not apply to information held solely by the private sector; however, information held by the Home Office which was provided by the private sector for regulatory purposes (e.g. a project licence application) is subject to FOIA in a manner identical to information provided by the public sector. Any information held by any public authority is subject to FOIA irrespective of its origins, although exemptions may apply where appropriate.
- **The public and interested groups (e.g. animal welfare and protection groups).**  
This group will have access to greater amounts of information than was previously publicly available. A demonstrable commitment to openness will help ensure the public fully understand the rationale behind the continued and necessary use of animals in scientific experiments.

### **A.3 Consultation**

#### **Within Government**

An inter-departmental group has been consulted extensively during the development of initial policy options. Expert advice has been sought from the Ministry of Justice, Home Office Legal Adviser's Branch and the Department for Business, Innovation and Skills; the Information Commissioner's Office, responsible for regulating the use of S24 to prevent disclosure under FOIA, has also been consulted.

#### **Interest Groups**

Regular meetings have been held with the UK bioscience sector, funding bodies, animal welfare groups, animal protection groups, practitioners and others with an interest in the use of animals in scientific research. Initial workshops were held in July 2013, to collate opinions on Section 24 from a wide-ranging group of stakeholders. Key issues from these were taken to further (separate) stakeholder workshops, focus groups and one-to-one meetings. All advice received has been taken into consideration in order to formulate initial policy options.

#### **Public Consultation**

This impact assessment accompanies a public consultation. This consultation sets out the Government's proposed options for the review. The consultation invites suggestions as to whether these options are appropriate, how they may work in practice and any alternatives available. We also seek advice to help quantify the impacts associated with the chosen options.

## **B. Rationale**

The use of animals in scientific procedures is an emotive issue that continues to polarise opinion. Animal research is a vital tool for understanding biological systems and is a crucial pathway in the development of medicines and medical technologies for the benefit of animals and humans, in addition to the protection of the environment. The Government has a duty to keep the public informed of the continued and necessary use of animals in scientific research, while ensuring we

uphold our high standards of animal welfare through rigorous yet efficient regulation. The use of animals in scientific research is part of a life sciences sector that contributes over £50bn to the UK economy every year – both through world-leading industry and a strong academic research base.

Government has a longstanding commitment to review Section 24 (see Background A.1, above). In addition to this, the Government will soon publish a Delivery Plan for the Coalition Commitment: ‘To work to reduce the use of animals in scientific procedures’, which provides a narrative of the rationale for the use of animals in scientific research and a framework of measurable actions to progress the commitment. Within this is a demonstration of our commitment to build on the Declaration of Openness launched last year, driven by the academic sector, health charities and industry. This commits those engaged in research to foster an environment of openness around the ways in which animals are used in scientific research in the UK.

Consequently, the inflexible confidentiality requirements of Section 24 are now out of step with government (and duty holder) policy on openness and transparency, in addition to the approach taken in other legislation, such as FOIA and the recent transposition of the European Union Directive (2010/63/EU) - the UK is now required to publish non-technical summaries of all authorised project licences. The review of Section 24 provides an opportunity to continue the progression to an increasingly open and transparent environment in which we are the monopoly regulator. Stakeholder feedback from initial engagements regarding Section 24 indicates that the current provision has little support and prevents greater openness where this would be desirable to foster public confidence in the regulation of animal research and testing.

Extensive stakeholder engagement has also highlighted the lack of clarity over who the legislation applies to and the coverage that it provides, including the confusion that arises from where the current Section 24 legislation interacts with FOIA, as highlighted by the House of Commons post-legislative scrutiny of the Act. The drive for a more transparent regulatory system allows us the additional opportunity to minimise this confusion and the associated regulatory burden on ourselves and duty holders. Amending the legislation will allow for consistent and simplified dissemination of information (including, but not limited to, where it is requested under FOIA). Alongside a demonstrable commitment to openness, this will ideally strengthen public and stakeholder confidence and trust in our duties as a regulator.

The sectors dependent on the use of animals for experimental and other scientific purposes have an estimated 100,000 employees, many in highly-skilled and highly-paid jobs. These sectors make a significant contribution to the UK economy, which may be at risk if the UK is perceived as too high-risk an environment to operate in. This perception may be exacerbated if we fail to provide sufficient protection to public health and safety and intellectual property, or if we place a disproportionate regulatory burden on public authorities and business. Our commitment to openness must be balanced by the provision of appropriate protection for sensitive information and the minimisation of the aforementioned regulatory burden. Stakeholders across the spectrum of opinion are in agreement that information that must be protected so long as it remains sensitive, and therefore not in the public interest to be released, includes that containing people and place details and intellectual property.

We must continue to protect public health and safety and the competitiveness of the UK life sciences, while ensuring the public fully understand the rationale behind the continued and necessary use of animals in scientific experiments. A demonstrable commitment to openness aids the construction of an informed public dialogue, helping to mitigate public anxieties and foster a culture of openness and understanding.

## **C. Objectives**

There is a requirement for a more flexible framework that will protect personal safety, proprietary rights and intellectual property, while providing greater transparency to assist public understanding about the use of animals in scientific procedures. It is imperative that the amended legislation does not harm the competitiveness of the UK in the life sciences and retains the confidence and trust of the UK life sciences sector (and the public) in our duties as a regulator.

It is not our objective to provide information so the public or other external bodies can conduct their own harm / benefit analysis as to whether a particular project should be initiated. In any event, such a harm / benefit analysis would not be possible without access to all the information provided about the project licence application, some of which (e.g. intellectual property) would be prohibited from public disclosure. The Home Office must remain the competent authority for taking decisions on licence applications.

Stakeholder engagement has demonstrated a lack of understanding as to the application of Section 24, and any amendment must clarify the extent to which the legislation can be applied and the information covered by it released. The new framework should not lead to disproportionate regulatory burdens being placed on public authorities or business.

## D. Options

Option 1: Is to make no changes (do nothing). The following table indicates how sensitive information is protected under the current legislation:

Classes of information	Protection provided for sensitive information	
	FOIA exemptions (particularly S.22, S.36, S.38, S.40, S.41, S.43 and S.44)	Statutory prohibition on disclosure (provided by the current Section 24 legislation)
<ul style="list-style-type: none"> <li>• Licence applications, supplementary information and recommendations</li> <li>• ASRU generated information, including inspectorate reports (assessment / visit / infringement) and associated correspondence</li> <li>• Section 12 and non-compliance documentation (including legal advice, reports, inspectorate advice and associated correspondence)</li> <li>• Ministerial and policy advice</li> <li>• ASC records</li> </ul>	Any of the exemptions may apply where relevant	Information is covered only where it contains information provided in confidence

*FOIA exemptions (further detailed in **Annex A**)*

- S.22 – Information intended for future publication
- S.36 – Prejudice to effective conduct of public affairs
- S.38 – Health and safety
- S.40 – Personal information
- S.41 – Information provided in confidence
- S.43 – Commercial information
- S.44 – Prohibitions on disclosure

Option 2.a: This option is to repeal Section 24 and amend ASPA by creating a criminal offence of malicious disclosure of information about the use of animals in scientific research. This option would require a legal definition of what constitutes malicious disclosure in these circumstances. This will be defined in the legislation, but may, for example, cover where information was disclosed with the intent to

cause harm or for financial gain. Definitions of what constitutes intellectual property (and information that might become commercially valuable in the future) may also be required. This option would allow for controlled release of information in required circumstances, in addition to non-malicious disclosure of confidential information, e.g. to highlight malpractice and / or threats to animal welfare. The following table indicates how sensitive information would be protected under the new legislation:

Classes of information	Protection provided for sensitive information	
		FOIA exemptions (particularly S.22, S.36, S.38, S.40, S.41, S.43 and S.44)
<ul style="list-style-type: none"> <li>As option 1</li> </ul>	Any of the exemptions may apply where relevant	Information is covered where it is released with malicious intent (defined in the legislation).

Option 2.b: This option is identical to option 2.a, with the addition of a statutory prohibition on disclosure of information that relates only to people and place details or intellectual property. The following table indicates how sensitive information would be protected under the new legislation:

Classes of information	Protection provided for sensitive information		
		FOIA exemptions (particularly S.22, S.36, S.38, S.40, S.41, S.43 and S.44)	Criminal offence for malicious disclosure
<ul style="list-style-type: none"> <li>As option 1</li> </ul>	Any of the exemptions may apply where relevant	Information is covered where it is released with malicious intent (defined in the legislation).	Information is covered where it relates only to people and place details or intellectual property.

Option 3: Is to repeal Section 24 in full. The following table indicates how sensitive information would be protected under the new legislation:

Classes of information	Protection provided for sensitive information
<ul style="list-style-type: none"> <li>As option 1</li> </ul>	Any of the exemptions may apply where relevant

## E. Appraisal (Costs and Benefits)

### GENERAL ASSUMPTIONS & DATA

By amending or changing the legislation, there may be changes to the way the public request or obtain information through FOIA. It has not been possible to quantify the change expected in FOI requests following the proposed amendments to the legislation. The average costs for answering FOI requests (staff time only) are estimated at £184 and £164 for central government and other public authorities respectively.<sup>2</sup>

All of the policy options are contingent on the application of FOIA in some way. However, clarity on the relevant exemptions within FOIA is necessary to ensure that the design of any new legislation achieves the outcomes we expect and require; ensuring FOIA provides appropriate transparency and security to information and minimising unnecessary overlap. The relevant exemptions in FOIA that can be applied (where they are relevant to the information) are listed in **Annex A**.

#### **Option 1 – No change to policy**

##### **COSTS (non-monetised)**

There will be no additional costs of option 1. However, there will be a number of risks that will continue to arise. These are detailed in section F.

##### **BENEFITS (non-monetised)**

There will be no additional benefits to option 1.

#### **Option 2 – Repeal Section 24 and replace with a criminal sanction for malicious disclosure**

##### **a) No additional statutory prohibition on disclosure**

##### **COSTS (non-monetised)**

###### *Provision of information*

- The cost of implementing changes to Section 24 is considered low. Legislative changes to greater transparency would have some resource implications for the greater provision of publicly accessible information (e.g. answering FOI requests). As mentioned above, the average costs for answering FOI requests (staff time only) are estimated at £180 and £160 (2012 prices) for central government and other public authorities respectively. As an indication of current levels, ASRU received 62 FOI requests in the 2013 calendar year. A hypothetical 10% increase in FOI requests would lead to an increased cost (staff time only) of £1100 per annum<sup>3</sup>. Anecdotal evidence from higher education bodies suggests a recent rise in FOI requests relating to the use of animals in scientific research.
- There is no intention to introduce the ability for the request of information that was produced before the introduction of the legislation. This would introduce a potentially significant cost burden and secondly, the information would not be available in a way commensurate with its later release.

##### **BENEFITS (non-monetised)**

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<sup>2</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/217390/investigative-study-informing-foia.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/217390/investigative-study-informing-foia.pdf)

<sup>3</sup> Note figures may not sum due to rounding.

- By providing for the potential release of much greater amounts of information than was previously publicly accessible, there may be a positive impact on public confidence by allowing for much greater transparency and assistance in the public understanding of the use of animals in scientific research.
- The greater amount of information that would potentially be publicly available may increase awareness among the scientific community of current research involving the use of animals, providing a constructive dissemination of technical knowledge and minimising duplication of animal experiments. For both UKBS and Government, the amendment to the legislative framework and the ability to disclose information more readily may provide for a reduction in the effort associated with the application for, and assessment of, licence applications. The legislation may also provide for the possible structured release of information that is deemed appropriate to be disclosed to the public.
- A criminal sanction that is applicable only in the instance of malicious disclosure of information may reassure the scientific community that the information they provide will be effectively protected from such disclosure. At the same time, the public and the animal welfare / protection sector will be reassured that genuine acts of “whistle blowing” could occur without breaking the law.
- The proposed option removes the inflexible confidentiality requirements of Section 24 and reduces the confusion surrounding its application. However it does little to address the uncertain application of FOIA exemptions to the information which it is agreed should be protected: i.e. people, places and intellectual property. It would therefore do little to reduce the risk of challenge arising from not providing information relating to the use of animals in scientific research when requested under FOIA.
- This option would provide some assurance for the UKBS that information provided in confidence by duty holders to the Government would retain appropriate protection, and would be unlikely to be maliciously disclosed.

#### **ONE-IN-TWO-OUT (OITO) N/A**

#### **b) With additional statutory prohibition on disclosure of information relating only to people and place details and intellectual property**

##### **COSTS (non-monetised)**

- The costs associated with this option are similar to those for option 2.a but may possibly be smaller as outlined in the benefits section.

##### **BENEFITS (non-monetised)**

- The benefits associated with this option include all those for option 2.a. However the uncertainty of relying entirely on FOIA is removed.
- There would be additional protection (in the form of a statutory prohibition on disclosure) provided for information which falls into the widely agreed category of that which should be protected: i.e. people, places and intellectual property. Consequently, there would be greater assurance for the UKBS that information provided in confidence by duty-holders to the Government retained appropriate protection, in addition to that provided by FOIA. ASPA is unique in that it requires duty-holders to provide detailed information about their most valued assets – their ideas and scientific hypotheses – in order to be permitted to pursue these ideas within the scientific research in question. This places especial responsibility on Government to ensure the absolute protection of this information. This option would be less likely (than 2.a) to induce a perception of there being insufficient protection provided for confidential information, and consequently the UK would be less likely to appear as a high-

risk environment to operate in. This may potentially mitigate concerns of a possible loss of investment in the UKBS, and the corresponding negative impact on the UK economy.

#### **ONE-IN-TWO-OUT (OITO) N/A**

#### **Option 3 – Repeal Section 24**

##### **COSTS (non-monetised)**

- The costs associated with this option would be similar to those outlined for option 2.a and 2.b; however the costs may be larger owing to the greater amount of information that would be publicly accessible. As detailed for option 2.a, there may be resource implications for the greater provision of publicly accessible information (e.g. answering FOI requests).

##### **BENEFITS (non-monetised)**

- By providing for the potential release of much greater amounts of information than was previously available, there may be a positive impact on public confidence by allowing for much greater transparency and assistance in the public understanding of the use of animals in scientific research.

#### **ONE-IN-TWO-OUT (OITO) N/A**

## **F. Risks**

#### **Option 1 - Do nothing.**

- By making no change to the legislation, this option fails to address the Government's commitment to increasing openness and transparency. This lack of action may induce a negative public perception towards our operation as a regulator and the use of animals in scientific research. Animal research is a high profile issue that continues to polarise opinion; this option will not counteract the negative opinion among certain members of the public that the Government applies Section 24 as a means to withhold information that should otherwise be publicly accessible. There is a risk that the Government is perceived to be inadequately dealing with the issue of assisting public understanding surrounding the use of animals in scientific procedures.
- This option would not resolve concerns expressed during post legislative scrutiny of FOIA about Section 24. These centred on a perceived contradiction between FOIA and ASPA, a lack of clarity about who may rely on Section 24, and concerns that institutions may be vulnerable to prosecution should they release information under FOIA. Extensive stakeholder consultation has reaffirmed the lack of clarity over who is covered by the current statutory prohibition.
- Public bodies involved in the use of animals in scientific research have indicated a recent rise in the number of FOIA requests received. The lack of clarity over who the current legislation applies to undermines the consistent dissemination of relevant information (from both Government and external public bodies) that has been requested by the public.

#### **Option 2 - Repeal Section 24 and replace it with a criminal offence of “maliciously” disclosing information about the use of animals in scientific research**

##### **a) No additional statutory bar**

### *Protection of confidential information*

- It is an imperative that we give public assurance and retain confidence in the use of animals in science within the UK. This option could see the UK adopt a framework that puts the UKBS at a competitive disadvantage due to a possible perception of there being insufficient protection provided for confidential information, as all information relating to the use of animals in scientific procedures could be released into the public domain, provided it was not done so with malicious intent and was not exempt from release under FOIA. This may lead to an increased risk of loss of investment in the UK life sciences sector, with a resultant negative impact on UK economic growth.
- There is a likely release of more information than at present. An increase in the amount of publicly available information may lead to an increased risk of identification of key confidential information (including people and place details and intellectual property). This may endanger public health and safety and consequently there may be a physical risk to those involved in the use of animals in scientific research. This includes the possibility of extremist activity and a potential need for increased security. It is difficult to assess the likelihood of this scenario although the occurrence of such activity has decreased in the past decade. However, it is nonetheless recognised that the exemption in section 38 of FOIA provides protection for information likely to endanger health and safety, and the Government strongly advises public authorities to make appropriate use of this provision.

### *Effective regulation*

- Key to the effective regulation of the use of animals in scientific procedures is the licensing regime. Lack of clarity over what constitutes protected and non-protected information within licence applications (i.e. that indicated by the legislation) could lead to confusion over the drafting and assessment of said applications. Currently, licence applications are not written for public consumption and the content could be misleading if released out of context. This apprehension could increase the regulatory burden (of the licensing process) on the UKBS and the Home Office, and associated financial consequences could include both the increased labour costs (both sides) or possible loss of competitive advantage (UKBS) due to the increased time taken. In 2012, there were 2,639 individual licences and 626 project licences granted, with the number per inspector FTE being 149.1 and 35.4 respectively.
- For the UKBS and Government, there may be a risk of incurring training and familiarisation costs associated with the changes to the legislation e.g the aforementioned drafting of a project licence application, including possible separation of confidential (or protected) information from that which is not confidential (or protected). The Government must provide clarity and assurance to those submitting confidential information to the HO that certain information will be protected, in order to maintain confidence and trust in ASRU's regulatory duties.

### **b) With additional statutory prohibition to protect people and place details and intellectual property**

- The risks would be similar to those for option 2.a. However, the addition of a statutory prohibition on disclosure of information relating only to people and place details and intellectual property may mitigate the above concerns regarding insufficient protection for confidential (or protected) information. As mentioned in the benefits section, the alleviation of such concerns may potentially prevent an increased risk of loss of investment in the UKBS, and the corresponding negative impact on UK economic growth if high quality science were to be driven overseas.

### **Option 3 - Repeal Section 24**

#### *Protection of confidential information*

- The risks associated with this option would be similar to those outlined for option 2.a, albeit possibly to a greater extent owing to the increased amount of information that would be publicly accessible and the lack of alternative protection to that provided by FOIA. There would be no protection for confidential (or protected) information beyond that provided by the exemptions within FOIA, including information that had been maliciously disclosed (e.g. that which is disclosed with the intent to harm public health and safety or for financial gain). While there is a lack of evidence to suggest that relevant FOIA exemptions are inadequate, there is a risk of a perception developing that the UK provides insufficient protection for the health and safety of those involved with animal research and the associated intellectual property. This may lead to an increased risk of loss of investment in the UKBS, with a resultant negative impact on UK economic growth if high quality science were to be driven overseas.
- The risk of malicious disclosure of information relating to the use of animals in scientific research may be greater than anticipated e.g. a disgruntled employee or student. This option would do little to prevent such disclosure and may therefore make the UKBS more vulnerable to loss of high value information, such as intellectual property or commercially valuable research ideas.

## **G. Enforcement**

We intend to consult on the proposed options, how they may work in practice and any alternatives available. Any amendments to the legislation, and the subsequent enforcement, will be decided following finalisation of a chosen option.

## **I. Implementation**

The consultation invites suggestions as to whether these options are appropriate, how they may work in practice and any alternatives available. We also seek advice on the level of consideration we have given to the impacts associated with the chosen options. A Government Response to the Consultation paper will be published after the consultation process has been completed and the government has taken a view on how to proceed.

Primary legislation would be required to introduce option 2.a or 2.b. The order making power within FOIA (Section 75) could be used to enact option 3.

## **J. Monitoring and Evaluation**

If, following consultation, the Government decides to opt for legislative change, objectives would be set and normal post-legislative scrutiny would be undertaken to establish whether those objectives had been met. The Justice Committee suggested (within the post-legislative scrutiny of FOIA) that it would consider the outcome of the Section 24 review upon completion by the Home Office.

## **K. Feedback**

The consultation seeks views on the proposed amendments to Section 24, and any other relevant additional information, including possible vehicles for implementation and the release of extra information into the public domain. As part of the process we will seek feedback from those involved in animal research, the animal welfare and protection sector, Home Office staff (including the ASRU inspectorate) and the general public. We have been working and will continue to work closely with the Department for Business, Innovation and Skills and Ministry of Justice to ensure their advice and expertise is fully incorporated into the proposed policy options. The Information

Commissioner's Office will likely be involved in the regulation of the results of the policy amendments in so far as they relate to FOIA and their views will be taken into account.

## **Annex A**

### **Freedom of Information Act 2000: Exemptions**

The Freedom of Information Act (FOIA) contains exemptions to the right of access. The exemptions listed in Part II of FOIA set out the circumstances in which public authorities may decline to provide information in response to any request: if information is exempt then individuals do not have a right of access to it under the Act. The exemptions ensure a proper balance is achieved between the right to know, the right to personal privacy, the delivery of effective government and other legitimate interests. Exemptions may, where appropriate, be used to refuse to confirm or deny whether information is held, or to decline to provide information that it is confirmed the public authority holds.

Some exemptions are 'absolute', that is, if the exemption applies then there is no obligation under the Freedom of Information Act to release the requested information (although there may be scope, or obligations, for other reasons outside the Act to do so).

For other exemptions, public authorities are required to assess the balance of the public interest for and against disclosure. These exemptions are often referred to as 'qualified', because they do not justify withholding information unless, on a proper assessment, the balance of the public interest is against disclosure. Some of these exemptions also contain a prejudice test, which means that they can only be used where a degree of likely harm can be demonstrated, rather than in relation to an entire class of information.

Section 21: information accessible by other means

Section 22: information intended for future publication

Section 23: information supplied by, or related to, bodies dealing with security matters

Section 26: defence

Section 27: international relations

Section 28: relations within the UK

Section 29: the economy

Section 30: investigations and proceedings conducted by public authorities

Section 31: law enforcement

Section 32: court records

Section 33: audit functions

Section 34: parliamentary privilege

Section 35: formulation of government policy

Section 36: prejudice to effective conduct of public affairs

Section 37(1)(a): communications with Her Majesty, with other members of the Royal Household

Section 37(1)(b): the conferring by the Crown of any honour or dignity

Section 38: health and safety

Section 39: environmental information

Section 40: personal information

Section 41: information provided in confidence

Section 42: legal professional privilege

Section 43: commercial interests

Section 44: prohibitions on disclosure

Sections 12 and 14 of FOIA also provide procedural grounds under which a request may be refused. Requests may be refused on cost grounds under section 12 and on the basis that they are repeated and/or vexatious under section 14.